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PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number (Optional) 022719-0046	
	Application Number 10/642,772-Conf. #3663	Filed August 18, 2003
	First Named Inventor Meir Rosenberg	
	Art Unit 3736	Examiner J. G. Hoekstra

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 44,238
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____

Signature

Lisa Adams
Typed or printed name

(617) 439-2000
Telephone number

April 27, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of 1 forms are submitted.

Pre-Appeal Brief Request for Review

I hereby certify that this correspondence is being electronically filed via EFS-Web to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date set forth below.

Dated: April 27, 2007 Signature: _____ (Lisa Adams)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Meir Rosenberg	
Application No.:	10/642,772	Group Art Unit: 3736
Filed:	August 18, 2003	Examiner: Jeffrey Gerben Hoekstra
Entitled:	TRIMMABLE SENSING CATHETER	
Docket No.:	22719-46 (COD-5013)	

Certificate of Transmission (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being electronically filed via **EFS-Web** to: **MS Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date set forth below.

Apr. 27, 2007 — By: [signature]

Date of Signature and Mail Deposit

Lisa Adams, Reg. No: 44,238
Attorney for Applicant(s)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENTS FOR PRE-APPEAL BRIEF REVIEW

Dear Sir:

These comments are being filed concurrently with a Notice of Appeal, and a Pre-Appeal Brief Request for Review.

A clean version of the ***Pending Claims*** is attached hereto.

REMARKS

Claims 1-27 are pending and stand rejected.

Claims 1-11, 13, and 15-27

Claims 1-11, 13, and 15-27 stand rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent 5,291,896 to Fonger et al. ("Fonger") in view of U.S. Publication 2003/0097082 to Purdy et al. ("Purdy"). The Examiner argues that Fonger teaches the claimed invention except for "(a) the distally disposed pressure sensor embedded in a distal portion of the catheter and (b) the at least one wire having a proximal end mated to an external antenna." The Examiner relies on Purdy to teach these features, arguing that it would have been obvious to modify the device of Fonger in view of Purdy to arrive at the claimed invention.

The pending rejection is deficient because the Examiner has not established a prima facie case of obviousness in support of the pending rejection. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference, or references when combined, must teach or suggest all of the claim limitations. The Examiner has failed to meet at least the first and second criteria.

With respect to the first criteria, the Examiner has failed to provide a suggestion or motivation to modify Fonger in view of Purdy. In the Advisory Action, the Examiner argues that one would be motivated to modify the device of Fonger to include the embedded pressure sensor and antenna as taught by Purdy to increase the "efficacy of a pressure measurement device" and to increase "patient safety during advanced medical procedure requiring pressure management whilst draining fluid." Fonger, however, already provides a sensor located on a probe extending from a tube. It is unclear how embedding this sensor would increase either the efficacy of the device or patient safety. In fact, as described below, embedding the sensor in the tube would render the Fonger device *inoperable* for its intended use – not more effective. Additionally, as explained in the second full paragraph on page 4 of the Amendment and Response Pursuant to 37 C.F.R. §1.116 filed on

March 29, 2007, there is no need include an antenna for remotely communicating with or energizing the Fonger device because Fonger discloses a *temporary* cardiac output probe assembly that is used post-operatively to monitor a patient *during recovery in the hospital.*

With respect to the second criteria, the Examiner has failed to show a reasonable expectation of success when modifying Fonger in view of Purdy. No person having ordinary skill in the art would modify Fonger to include a distally disposed pressure sensor that is embedded in a distal portion of the catheter because such a modification would require a change in the basic principal under which the Fonger construction was designed to operate, and it would render the Fonger device inoperable for its intended use. Applicant refers the review panel to arguments previously presented and set forth in the last paragraph starting on page 2 and the first full paragraph on page 3 of the Response filed on November 15, 2006 in addition to arguments presented in the last full paragraph on page 3 of the Response Pursuant to 37 C.F.R. §1.116 filed on March 29, 2007.

First, modifying Fonger to embed the pressure sensor on the tube changes the principal operation of the Fonger device. The basic principle of Fonger is to provide a probe with tines for attaching a pressure sensor on the probe to a blood vessel. The probe is specifically configured to extend from a tube to allow the probe to attach to an exterior surface of a vessel. Modifying the device to put the sensor on the tube, rather than the probe, changes the principle operation of the device from detection via *implantation* in an exterior surface of an artery or vessel to detection via *insertion* in an artery or vessel. As set forth in the Manual of Patent Examining Procedure (MPEP), a proposed modification cannot change the principle operation of a reference. MPEP 2143.01(VI); see also *In re Ratti*, 270 F.2d 810 (CCPA 1959).

Second, modifying Fonger to embed the pressure sensor on the tube would render the Fonger device inoperable for its intended use. MPEP §2143.01(V) states that "[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." If the device of Fonger were modified to include a sensor embedded in a sidewall of the tube, as suggested by the Examiner, then the sensor could not be used for its intended purpose. Namely, if the sensor were located on the tube it could not be attached to an external surface of a blood vessel to measure cardiac output.

Accordingly, the Examiner has failed to establish a prima facie case of obviousness, and therefore claims 1-11, 13, and 15-27 distinguish over Fonger and Purdgy, taken alone or combined, and represent allowable subject matter.

Claims 12 and 14

Claims 12 and 14 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Fonger in view of Purdy, as applied to claims 1-11, 13, and 15-27, and further in view of U.S. Patent 5,104,398 to Quackenbush ("Quackenbush").

Claims 12 and 14 depend from claim 1, and therefore distinguish over Fonger and Purdy for the same reasons discussed above with respect to claim 1. Quackenbush is merely relied on by the Examiner to teach "the polymer selected from a group consisting of silicones, silicone-like materials, and polyurethanes and wherein the at least one wire is disposed within a secondary catheter coupled to the first that can be peeled apart to allow the catheter length to be adjusted independent the length of the secondary catheter," as recited in claims 12 and 14. Accordingly, Quackenbush does not remedy the deficiencies of these references. Claims 12 and 14 therefore represent allowable subject matter.

Conclusion

In view of the above remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested.

Respectfully submitted,

Date: April 27, 2007

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PENDING CLAIMS

1. (Previously Presented) An implantable fluid management device, comprising:

an elongate catheter having a proximal end, a distal end, and a first inner lumen extending therethrough;

a sensor embedded in a distal portion of the catheter such that the sensor is effective to measure a pressure of fluid surrounding the distal portion of the catheter;

at least one wire having a distal end coupled to the sensor and having a proximal end that is adapted to mate to an external component for powering and/or communicating with the sensor, the at least one wire extending along a length of the catheter such that the at least one wire is in fluid isolation from the inner lumen of the catheter, and the at least one wire being separable from a proximal portion of the catheter such that the length of the catheter is selectively adjustable.

2. (Original) The device of claim 1, wherein the at least one wire is disposed within a second lumen that is isolated from the first lumen.

3. (Original) The device of claim 2, further comprising a slit extending through an outer wall of the catheter into the second lumen, the slit extending along at least a portion of a length of the catheter from the proximal end thereof such that a portion of the at least one wire can be at least partially removed from the catheter through the slit to allow the length of the catheter to selectively adjusted.

4. (Original) The device of claim 2, wherein the first lumen has a diameter that is greater than a diameter of the second lumen.

5. (Original) The device of claim 2, wherein the second lumen is formed within an invagination of the outer wall of the catheter extending within the first lumen.

6. (Original) The device of claim 1, further comprising a slit extending through an outer wall of the catheter along at least a portion of a length of the catheter from the proximal end thereof such that

a portion of the at least one wire can be at least partially removed from the catheter through the slit to allow the length of the catheter to selectively adjusted.

7. (Original) The device of claim 6, wherein the slit extends along a distance less than the length of the catheter.

8. (Original) The device of claim 6, wherein the slit extends along less than about one half of the length of the catheter.

9. (Original) The device of claim 6, wherein the slit is substantially fluid impermeable in a closed position.

10. (Original) The device of claim 6, wherein the catheter is made from a material that is self-sealing.

11. (Original) The device of claim 6, wherein the at least one wire is disposed within a second lumen that is isolated from the first lumen and the slit extends into the second lumen.

12. (Original) The device of claim 1, wherein the at least one wire is disposed within a secondary catheter that is coupled to the catheter and that can be peeled apart from the catheter to allow the length of the catheter to be selectively adjustable, independent of the length of the secondary catheter.

13. (Original) The device of claim 1, wherein the catheter is formed from a flexible, biocompatible polymer.

14. (Original) The device of claim 1, wherein the catheter is formed from a polymer selected from the group consisting of silicones, silicone-like materials, and polyurethanes.

15. (Original) The device of claim 1, wherein the sensor is disposed with a wall of the catheter such that the sensor is adapted to sense conditions adjacent to the catheter.

16. (Original) The device of claim 1, wherein the sensor is a pressure sensor.

17. (Original) The device of claim 1, wherein the sensor has a diameter that is equal to or less than about 3 mm.

18. (Previously Presented) An implantable fluid management device, comprising:

an elongate catheter having a proximal end, a distal end, and first and second inner lumens extending therethrough and isolated from one another;

a sensor disposed at a distal portion of the catheter;

at least one wire extending through the second lumen in the catheter and having a distal end coupled to the sensor and a proximal end mated to an external antenna; and

a slit extending through an outer wall of the catheter into the second lumen along at least a portion of a length thereof such that a portion of the at least one wire can be at least partially removed from the catheter through the slit to allow the length of the catheter to be selectively adjustable.

19. (Original) The device of claim 18, wherein the first lumen has a diameter that is greater than a diameter of the second lumen.

20. (Original) The device of claim 18, wherein the second lumen is formed within an invagination of the outer wall of the catheter extending within the first lumen.

21. (Original) The device of claim 18, wherein the slit extends along a distance less than the length of the catheter.

22. (Original) The device of claim 18, wherein the slit extends along less than about one half of the length of the catheter.

23. (Original) The device of claim 18, wherein the slit is substantially fluid impermeable in a closed position.

24. (Original) The device of claim 18, wherein the catheter is made from a material that is self-sealing.

25. (Original) The device of claim 18, wherein the catheter is formed from a flexible, biocompatible polymer.

26. (Original) The device of claim 18, wherein the sensor is disposed with a wall of the catheter such that the sensor is adapted to sense conditions present around the catheter.

27. (Original) The device of claim 18, wherein the sensor is a pressure sensor.

28-35. (Canceled).

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